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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/770,123   | 02/03/2004  | Corinna Sundermann   | 029310.53175US      | 7253             |
| 23911  | 7590        | 10/24/2006           | EXAMINER            |                  |
| CROWELL & MORING LLP<br>INTELLECTUAL PROPERTY GROUP<br>P.O. BOX 14300<br>WASHINGTON, DC 20044-4300 |             |                      | AULAKH, CHARANJIT   |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1625                |                  |

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/770,123             | SUNDERMANN ET AL.   |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Charanjit S. Aulakh    | 1625                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 September 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 47-52 is/are rejected.
- 7) ☒ Claim(s) 25-46 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. According to paper filed on Sep. 15, 2006, the applicants have amended claims 50-52.
2. Claims 1-52 are pending in the application.

### ***Response to Arguments***

3. Applicant's arguments filed on Sep. 15, 2006 have been fully considered but they are not persuasive regarding enablement rejection of claims 47-52 and obviousness rejections of claims 1-24. The examiner agrees with the applicant's arguments regarding both of Gerlach's references that these references do not constitute prior art references under 102(e) and 102(a). The examiner also agrees with the applicant's arguments regarding indefiniteness rejections. In regard to enablement rejection of instant claims 47-52, the examiner does not agree with the applicant's arguments that the specification is enabling for treating/inhibiting all conditions mentioned in instant claims 50-52 and alleviating pain. The applicants did not provide any references of well established utility of structurally closely related compounds in the diseases recited in instant claims 50-52. There are no working examples in the instant specification showing efficacy of instant compounds in known animal models of all these disease conditions listed in instant claims 50-52. The specification must be enabling for one of ordinary skill in the art to practice the invention with reasonable expectation of success without undue experimentation. In the instant case, the specification is enabling only for treating pain. In regard to alleviating pain, NMDA receptor antagonism is only one of the several other known mechanisms responsible for the etiology of pain and therefore, the

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instant compounds will have utility in treating but not alleviating ( completely curing ) pain.

In regard to obviousness rejections over Borrione and two Kobayashi's references, the examiner does not agree with the applicant's arguments on page 24, first and second paragraphs that the therapeutic utility or NMDA receptor activity of the instant compounds is due to salts of instant compounds and not the compounds themselves. The applicants have not provided any comparative data to substantiate this unexpected results. As stated clearly in the last office action, preparing salts of known compounds is within the routine skill of an artisan.

#### ***Conclusion***

4. Rejection of claims 47-52 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.
5. Rejections of claims 1-24 under 35 U.S.C. 103(a) over both of Kobayashi's references are maintained for the reasons of record.
6. Rejection of claims 1-9, 11 and 15-24 under 35 U.S.C. 103(a) over Borrione's reference is maintained for the reasons of record.
7. Claims 25-46 are objected as being dependent upon a rejected claim.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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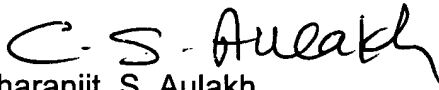
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Charanjit S. Aulakh  
Primary Examiner  
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